The effect of chronic nocturnal non-invasive ventilatory support at home after ventilatory support during acute respiratory failure in patients with Chronic Obstructive Pulmonary Disease (COPD).

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Does chronic nocturnal ventilatory support at home after acute respiratory failure treated by (N)IV lead to a prolongation in time to readmission to hospital due to any following exacerbations in these patients compared to medical treatment only?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON31750

Source
ToetsingOnline

Brief title
RESCUE

Condition

- Respiratory disorders NEC

Synonym
Chronic bronchitis, COPD

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Respironics Inc., Murrysville, PA, USA,UMCG;Respironics en Astma Fonds

Intervention

Keyword: Acute respiratory failure, COPD, Non-invasive ventilation

Outcome measures

Primary outcome

Time to event is the primary study outcome, for which an event is defined as a readmission to hospital due to an exacerbation or death. An exacerbation is defined using a modified version of the definition of Rodriguez-Roisin, as an event in the natural course of the disease defined as characterized by a change in the patient*s baseline dyspnoea, cough, and/or sputum that is beyond day-to-day variations, is acute in onset, and which is treated with an antibiotics course and/or prednisolon in patients with underlying COPD.

Secondary outcome

- Exacerbations

- Health related quality of life

- Total readmission rate

- Total event rate

- Survival

- Medical costs

- Dyspnoea

- Activities of daily living

- Blood gasses PaO2 and PaCo2

- Inflammation (systemic) markers

- Lung function

- Muscle strength

- Nutritional status

Study description

Background summary

Currently, chronic ventilatory support for patients with neuromuscular disease and kyphoscoliosis in the Netherlands is routinely managed by 4 home mechanical ventilation (HMV) centres. In contrast, there is no consensus yet how to treat patients with COPD with chronic respiratory failure after an acute event, due to the lack of studies in this area. However, some patients in the Netherlands do receive chronic non invasive ventilation (NIV) after an acute event, while no evidence is available about its effect in the Netherlands or elsewhere. This is the reason why we want to investigate if chronic nocturnal NIV at home is effective in unstable patients with COPD, who remain hypercapnic after ventilatory support during acute respiratory failure.

Study objective

Does chronic nocturnal ventilatory support at home after acute respiratory failure treated by (N)IV lead to a prolongation in time to readmission to hospital due to any following exacerbations in these patients compared to medical treatment only?

Study design

The protocol concerns a multi-centre, prospective, randomized, controlled study. It will take 2 years to include all 200 patients from which 100 will receive non-invasive ventilatory support at night at home as well as medical treatment, and 100 comprise the control group who will receive medical treatment only for the duration of 1 year.
The study will take place throughout the whole of the Netherlands, as 3 HMV (Home Mechanical Ventilation Centres) will cover the entire country. Each Centre for Home Mechanical Ventilation has its own nurse consultant. If a patient meets inclusion criteria the treating pulmonologist will contact the HMV centre that is responsible for chronic ventilatory support in that region.

The nurse consultant will then visit the patient in *his/her own* hospital where she will provide, if the patient has expressed willingness to enter the study, the written informed consent. The patient will then be randomised for either chronic NIV at home or for a control group receiving medication only. If the patient is randomised to the treatment group, she will firstly let him/her get used to NIV support whilst the patient is recovering in hospital. It will take approximately 10 days to recover from the acute exacerbation and during this period the patient can be properly adjusted to the NIV. During these days the patient will be asked by the nurse consultant to fill in 4 questionnaires and perform a 6-minute walking test. Lung function tests and blood gas analyses are standard procedure for treatment with NIV, and thus can be performed by the treating department of Pulmonology. After recovery from the exacerbation, the patient is discharged from the hospital, and NIV will be continued at home.

Intervention

Nocturnal noninvasive ventilatory support will be started by BiPAP (Bilevel Positive Airway Pressure) in the assist controlled mode (Synchrony, Respironics, INC, Murrysville, PA, USA) The respiration of the patient will be maximally supported to reduce the work of breathing. We will start with an IPAP (Inspiratory Positive Airway Pressure) of 14 cm H2O and an EPAP (Expiratory Positive Airway Pressure), of 4 cm H2O, Respiratory Rate (RR) of 12 /min, inspiration: expiration time 1:3, and a short rise time. We will start with a full face mask and add humidification in case of mouth dryness and nose problems. BiPAP will be set up aiming to ventilate the patient for at least 6 hours of sleep during the night.

Study burden and risks

A few studies, although somewhat limited in design, showed that NIV reduced readmission rates and improved survival. Other important potential benefits that may be realized by study participants include improved air exchange, a better quality of life, less dyspnoea and an improved quality of sleep. Both patients and non participating subjects can benefit from this study and its outcome, but it is also possible that subjects will not receive any benefit from treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Chronic Obstructive pulmonary disease (COPD), GOLD severity stage 3 and 4.
2) Minimally 48 hours without ventilatory support after invasive or non invasive ventilatory support during an acute respiratory failure and maximally until discharge.
3) Persistent hypercapnia ($PaCO_2$ > 6.0 kPa) during daytime at rest without ventilatory support.

Exclusion criteria

1) Age < 18 or =>80 years
2) Significant bronchiectasis with recurrent infections
3) Significant heart failure
4) Kyphoscoliosis
5) Neuromuscular disease
6) Obstructive sleep apnea (Apnea Hypopnea Index: AHI >15 /hr)
7) Current use of Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BiPAP)
8) Insufficient motivation for chronic ventilatory support;
9) Social circumstances making chronic ventilatory support impossible;
10) Other disease factors limiting life expectations

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2007
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Bilevel Positive Airway Pressure
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	10-08-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL18065.042.07